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NIXON & VANDERHYE, PC			JACOE, DONNA A	
901 NORTH GLEBE ROAD, 11TH FLOOR			ART UNIT	PAPER NUMBER
ARLINGTON, VA 22203			1614	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/613,723	<b>Applicant(s)</b> CUPFERMAN ET AL.
	<b>Examiner</b> Donna Jagoe	<b>Art Unit</b> 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 November 2007.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 14-34 is/are pending in the application.  
 4a) Of the above claim(s) 21-32 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 14-20,33 and 34 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/1449)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Claims 14-34 are pending. Claims 21-32 are withdrawn. Claims 14-20, 33 and 34 are rejected.***

Applicants' arguments filed November 6, 2007 have been fully considered and they are deemed to be persuasive regarding previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

However, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 14 that recites the term PEG-20 hexadecenyl succinate in lines 11-12 of the claim and PEG-15 stearyl ether in line 13 of the claim, it is customary that the full name of the abbreviation be recited the first time the abbreviation is used in the claims. The meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. Applicants

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need not confine themselves to the terminology used in the prior art, but are required to make clear and precise the terms that are used to define the invention whereby the metes and bounds of the claimed invention can be ascertained. During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969).

Claims 15-20 are indefinite to the extent that they read on the rejected base claim.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-20 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chambers et al. U.S. Patent No. 4,988,453 and Williams (U)

Chambers et al. teach a soap comprising anionic surfactants such as disodium ricinoleic acid monoethanolamide sulphosuccinate (Rewoderm S1333) (column 4, lines 54-60) in an amount of up to 10% (column 4, lines 20-24). It does not teach 0.1-100 % or 0.5-50% or 1-25%, however, the amount recited, up to 10% is encompassed by the claimed amounts. One skilled in the art would have been motivated to prepare additional useful compositions of the ranges taught by the prior art. While the reference is silent regarding some % ratios, the difference in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 45, 105 USPQ 233, 235 (CCPA 1955). In the absence of any criticality and/or unexpected results of the additional ranges claimed, the instant invention is considered obvious.

Chambers et al. does not teach the method of modifying the physicochemical properties of the surface of the skin to reduce adhesion of microorganisms.

Williams teaches that hand-washing is the most effective disease-preventing measure anyone can practice. Williams further teaches that antimicrobial soaps are unnecessary and hand washing with soap and water flushes away yeast, fungi and staph. It would have been obvious to employ a soap comprising the anionic surfactant disodium ricinoleic acid monoethanolamide sulphosuccinate of Chambers et al. in a soap composition for reducing adhesion of microorganisms motivated by the teachings of Williams that hand washing with soap and water flushes away microorganisms, including *S. aureus*.

While the reference is silent with respect to the amount of viable bacteria that would adhere to reconstructed epidermis after the treatment regimen as specified in the instant application, it is the position of the examiner that the functional limitations would be inherently met by the referenced compositions. As noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on

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"inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deckner et al. U.S. Patent No. 5,989,536 and Williams (U).

Deckner discloses personal cleansing compositions. A disclosed cleansing composition according to Deckner includes SEPIGEL 305, a mixture of polyacrylamide and C13-14 laureth-7 (7EO)(see col. 23, line 44 through col. 24, line 46). While the reference is silent with respect to the amount of viable bacteria that would adhere to reconstructed epidermis after the treatment regimen as specified in the instant application, it is the position of the examiner that the functional limitations would be obvious over the referenced compositions. As noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same.

It does not teach modifying the physicochemical properties of the surface of the skin or reducing the adhesion of *S. aureus* to the skin and/or the mucous membranes.

Williams teaches that hand-washing is the most effective disease-preventing measure anyone can practice. Williams further teaches that antimicrobial soaps are unnecessary and hand washing with soap and water flushes away yeast, fungi and staph. It would have been obvious to employ a personal cleansing composition comprising 7EO of Deckner et al. for reducing adhesion of microorganisms motivated by the teachings of Williams that hand washing with soap and water flushes away microorganisms, including S. aureus. Regarding the aspect of the claim drawn to reducing the decimal logarithm of the mean number of viable bacteria adhering to the reconstructed epidermis to at least 0.3 less when said epidermis is contacted with said compound compared to water as measured by contacting said epidermis with a test compound for 2 hours at 37 degrees, Williams teaches that hand-washing is the most effective disease-preventing measure anyone can practice and hand washing with soap and water flushes away yeast, fungi, and microorganisms, including staph and S. aureus. While the reference is silent with respect to the decimal log reduction of bacteria that would adhere to reconstructed epidermis after the treatment regimen as specified in the instant application, it is the position of the examiner that the functional limitations would be obvious over the referenced compositions.

#### ***Response to Arguments***

Applicant asserts that the terms PEG-20 and PEG-15 stearyl ether will be appreciated by one of ordinary skill in the art to refer to polyethylene glycol 20 and polyethylene glycol 15 stearyl ether. In response, there does not appear to be an

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explicit definition for the term "PEG 15 or PEG 20" in the specification. Thus, the term should be given its ordinary meaning and broadest reasonable interpretation; the term should not be limited to the industry standard definition of polyethylene glycol 20 or polyethylene glycol 15 where there is no suggestion that this definition applies to the term "PEG 15 and PEG 20" as claimed. Therefore, the terms can read on other embodiments.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./  
Examiner  
Art Unit 1614

March 4, 2008

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614

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